

Broad EPA PFAS Rule to Have Significant Impact for Manufacturers

On September 28, 2023, the U.S. Environmental Protection Agency (EPA) issued its [final rule under the Toxic Substances Control Act \(TCSA\)](#) mandating that businesses that have manufactured or imported PFAS chemicals—including importers of articles containing any PFAS—report extensive information on the chemicals going back to 2011.

Companies have just 18 months from the rule's November 13, 2023 effective date to report 10+ years of data. Businesses will need to take steps *now* to review their operations, product categories and supply chains to gather information on PFAS usage.

What Does the Rule Cover?

The EPA is required under Section 8(a)(7) of TCSA to collect information on PFAS manufactured and imported for commercial purposes. The rule therefore requires companies that have manufactured PFAS in any year since January 1, 2011, to electronically report certain information to the EPA, including:

- PFAS chemical identity;
- Categories of use (such as industrial processing, or consumer and commercial);
- Volumes manufactured, imported and processed;
- Byproducts;
- Environmental and health effects;
- Worker exposure; and
- Disposal.

The EPA's final rule includes an expanded and technical definition of PFAS which includes nearly 1,500 types of PFAS chemicals. The EPA is expected to publish the full list of substances online, but at least two of the regulated substances included are the well-known perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA).

What Businesses are Affected?

Short answer: more businesses are affected than currently realize it. Under the rule, any entity that manufactures, or has manufactured, PFAS chemicals for a commercial purpose is required to report to the EPA. However, the EPA has broadly defined "manufacturing" as producing, manufacturing, or *importing*

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covered PFAS for commercial purposes. "Commercial purposes" is defined broadly to include activities for which the purpose is to obtain commercial advantages, including commercial distribution, test marketing, use in product R&D and use as an intermediate.

The rule also requires manufacturers to report the presence of PFAS in mixtures and articles (i.e., finished consumer products) containing PFAS chemicals; accordingly, you must report if you qualify as either: (1) an entity that manufactures or imports PFAS; (2) an entity that manufactures or imports mixtures or compounds that contain PFAS; or (3) an entity that manufactures or imports articles (i.e., consumer products and their components) that contain PFAS.

Importantly, apart from timing for reporting (discussed below), the rule does not provide any exemptions for small businesses or *de minimis* quantities of PFAS.

How Does My Business Comply with the Rule?

The effective date of the rule is November 13, 2023. Reports for non-small businesses are due 18 months from the effective date of the rule, or May 2025.

Small businesses, on the other hand, will have an additional six months—until November 2025—to submit information.

- For purposes of section 8(a) of TSCA, "small manufacturers" are those who meet one of two standards: (1) a manufacturer (including importer) with total annual sales, when combined with those of its parent company, of less than \$120 million, and annual production (or importation) volume of a particular chemical substance not exceeding 100,000 lbs; or (2) a manufacturer (including importer) whose total annual sales, when combined with those of its parent company, are less than \$12 million.

Given the extensive reporting requirements, discussed more below, companies should begin preparing immediately to ensure compliance before the 2025 deadline.

Upcoming Requirements

I. Due Diligence/Investigation

Companies covered by the rule must collect reporting for all information in their "possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." This means that



companies must conduct what the EPA calls a "reasonable inquiry," both within and outside their organization, by methods including, but not limited to, placing phone calls or sending email inquiries "to upstream suppliers or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing of the PFAS."

On the other hand, the EPA states clearly in its pre-publication notice that the rule does not require companies to conduct surveys or conduct testing as part of their due diligence efforts. Still, the extent of inquiry necessary for products produced and imported more than ten years ago remains a significant question for companies trying to comply with the rule.

II. Reporting

For all manufacturing, importation or production activities from 2011 to the present, companies will need to report the following information to the EPA beginning in 2025:

1. Company and facility information;
2. Chemical identity and molecular structure;
3. Information concerning the industries in which PFAS is used and the purpose for such use;
4. Information concerning consumer and commercial use of PFAS and the purposes for such use;
5. Quantities of PFAS manufactured, produced or imported in each calendar year since January 1, 2011;
6. Description of the byproducts resulting from the manufacture, processing, use or disposal of PFAS chemicals, including information on any releases into the environment;
7. All existing information concerning the environmental and health effects" of the relevant PFAS chemical in the company's possession or control, which is not limited to information published since 2011;
8. Information concerning worker exposure, including the number of workers exposed, activities performed by the workers and exposure scenarios and duration; and
9. Information concerning disposal of PFAS, including the amounts of PFAS disposed and methods for disposal.

The EPA has specified a "streamlined" reporting form option for article importers, understanding that the amount of information "reasonably ascertainable" to



companies that merely imported articles (as opposed to the chemicals themselves or chemical mixtures) may be more limited. The streamlined form focuses on chemical identity, categories of use and production volume of the *imported article* (which may be easier to determine than the volume of the PFAS chemical) and does not require information on disposal and environmental and health effects.

What Steps Do I Need to Take Now That the Rule is Final?

Companies affected by the rule should immediately consider what processes they will implement to ensure they are prepared to report in 2025 and demonstrate sufficient due diligence.

Particularly critical to this consideration is the extent of the period covered. The EPA knew in its regulatory analysis conducted in 2022 the challenges that reviewing back to 2011 would pose on importers of manufactured “articles” who may not have the detail on the current presence of PFAS, much less historic presence. But the final rule has not significantly lessened that burden, other than the streamlined reporting option. Accordingly, companies need to develop a plan for finding and collecting the PFAS-related information “known to or reasonably ascertainable by” the company, and *carefully documenting the effort* to obtain such information to show compliance. Some details may be considered confidential business information (CBI), and companies will need to follow TSCA procedures for asserting CBI claims.

TSCA violations can trigger civil and criminal penalties. To ensure compliance during every step of this process, companies should involve legal counsel now to strategize on a plan moving forward.

For questions regarding the new rule or PFAS regulations in general, please contact [Patrick Hodan](#), [Guy Temple](#), [Danielle Marocchi](#), or any member of [Reinhart's PFAS Team](#).

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